

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alexascins, Virginia 22313-1450 www.emplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/595,734	05/22/2007	Richard Martin	06-132-A1	5512
63572 7590 039852000 O39852000 300 SOUTH WACKER DRIVE 300 SOUTH WACKER DRIVE			EXAMINER	
			JAISLE, CECILIA M	
SUITE 3100 CHICAGO, II	. 60606		ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			03/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/595,734 MARTIN ET AL. Office Action Summary Examiner Art Unit Cecilia M. Jaisle 1624 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 06 October 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-11.13.14 and 31-36 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-11,13,14 and 31-36 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

Art Unit: 1624

#### DETAILED OFFICE ACTION

# Lack of Unity

Applicants' confirmation of the election with traverse of Group I, claims 1-11, 13, 14 and 31-36 in the Response of 10-06-2008 is acknowledged. Claims 1-11, 13, 14 and 31-36 are under examination only to the extent that they are readable on the elected subject matter.

Applicants traverse on the grounds that pending claims are generic and request that the examination be extended to the non-elected portion of the generic claims. Applicants point to MPEP §§ 803.02 and 809 in support of their position. However, those portions of the MPEP relate to restriction practice, while the present situation of a holding of lack of unity. Accordingly, for all the reasons of record in the Office Action of June 5, 2008, this holding of lack of unity is deemed proper and is maintained.

### Rejections Under 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13, 14 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim subject matter which applicant regards as the invention.

Art Unit: 1624

# Claims 1, 2:

• In the Q1 definition, the recitation "substituents, when substituted, are independently substituted with ..." is not understood. It defines substituents (secondary) of substituents (primary), but does not define primary substituents. Since previous definitions of various optional substituents does not provide for substituted substituents, it is not understood what is meant by the situation defined as "when substituted." A single compound cannot be at times substituted and at other times unsubstituted.

### Claims 1-11, 13, 14 and 31-36:

- These are improper composition claims, because they fail to recite an ingredient other than the compound itself. Therefore, it is not possible to determine if these claims are intended to be interpreted as compound claims or as composition claims.
- "Pseudohalo" is not understood nor does the specification define it. Baker, et al., Inorganica Chimica Acta, Vol. 357, # 10, 20 July 2004, 2841-2849, discussing synthesis and structural characterization of (pseudo)-halo adducts of (n<sup>4</sup>-1,5-cyclooctadiene)(1,3-dimethylimidazolin-2-ylidine)rhodium, include NCO, N3, SCN, SeCN as pseudo-halide examples. Baker, et al., Dalton Trans. 2005 Jan 7;(1):37-43, discussing synthetic, structural and spectroscopic studies of (pseudo) halo(1,3-di-tert-butyl-imidazol-2-ylidine)gold complexes, include N3, NCO, SCN, SeCN, ONO2, OCOCH3, CH3 as pseudo-halide examples. Zalaudek, et al., J. Am. Acad. Dermat., Vol. 54, #, 1106-1107 (June 2006), describes pseudo-halo nevi as dark brown, variously-sized and partially elevated melanocytic nevi encircled by a depigmentation rim. According to Maurasse, pseudo-halo burrows have an external contour similar

Application/Control Number: 10/595,734 Page 4

Art Unit: 1624

to simple burrows but show off-center concentric layers of slightly different lithology unlike halo burros. <a href="http://www.deepseadrilling.org/15/volume/dsdp15\_24.pdf">http://www.deepseadrilling.org/15/volume/dsdp15\_24.pdf</a>; downloaded 12/31/2008. Pseudo Halo is also a recent offering from songster Malf. <a href="http://www.voutube.com/watch?v=voNM8bBBwbE">http://www.voutube.com/watch?v=voNM8bBBwbE</a>; downloaded 12/31/2008.

In R31, R34, R35, R36, R16 definitions, "alkoalkenvl" is not understood.

### Claim 14:

The claim is incomplete: importing limitations from the specification is improper.

### Claims 32, 34-36:

Parenthetical phrases, phrases "i.e.," "e.g.," "also known as," "such as," and
definitional phrases render the claims indefinite because it is unclear if the limitations
following the phrases are part of the claimed invention. MPEP § 2173.05(d).

#### Rejections Under 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1624

Claims 1-11, 13, 14, 31 and 33 are rejected under 35 USC 102(a) over Cai, et al., US 7226927, entitled to the date of Dec. 12, 2000, describing compositions as apoptosis inducers comprising 2-aryl-4-arylaminopyrimidines (see col. 6, lines 25-54, inter alia); also see compounds/compositions exemplified throughout the specification.

Claims 1, 11, 13, 14 and 31 are rejected under 35 USC 102(a) over Jiao, et al., US 6608066, entitled to the date of 19991027, describing compositions of RN 328265-49-2, 1H-Isoindole-5-carboxylic acid, 2-[4-[2-[4-(5-carboxy-1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)phenyli-4-pyrimidinyliphenyli-2.3-dihydro-1.3-dioxo-.

, as tissue

factor antagonists.

Claims 1, 11, 13, 14 and 31 are rejected under 35 USC 102(a) over Ahmad, et al., US 6887870, entitled to the date of 19991012, describing compositions of RN 335063-13-3, Pyrimidine, 4-chloro-6-[4-(4-methyl-1H-imidazol-5-yl)-1-piperidinyl]-2,5-diphenyl-,

, as heterocyclic sodium/proton exchange inhibitors.

Art Unit: 1624

Claims 1, 11, 13, 14 and 31 are rejected under 35 USC 102(b) over Chu-Moyer, et al., US 6414149, patented 20020702, describing compositions of RN 300550-97-4, 2-Pyrimidinemethanol, 4-[(2R,6S)-4-[2-(2-hydroxyphenyl)-4-pyrimidinyl]-2,6-dimethyl-1-piperazinyl]-a-methyl-, (aR)-,

, as sorbitol dehydrogenase inhibitors.

Claims 1, 11, 13, 14 and 31 are rejected under 35 USC 102(b) over Kinoshita, et al., WO 2000041999, published 20000720, describing compositions of RN 283599-15-5, Benzenepropanamide,  $\alpha$ -(methoxyimino)-N,2-dimethyl-5-(4-phenyl-2-pyrimidinyl)-,

RN 283599-62-2, Benzenepropanoic acid,  $\alpha$ -(methoxyimino)-2-methyl-5-(4-phenyl-2-pyrimidinyl)-, methyl ester,

Application/Control Number: 10/595,734 Art Unit: 1624

Claims 1, 11, 13, 14 and 31 are rejected under 35 USC 102(b) over Fauran, et al., US 4041030, issued 19770809, describing antianoxic compositions comprising

, wherein in Formula I, R

= H, halo, C1-3 alkoxy; R1 = H, Me; n = 0, 1; m = 0-3; exemplified by RN 65789-84-6, Morpholine, 4-[4-[[2-(4-chlorophenyl)-5,6-dimethyl-4-pyrimidinyl]amino]benzoyl]-,

Claims 1, 11, 13, 14, 31 and 33 are rejected under 35 USC 102(b) over Murata, et al., JP 2001139560, published 20010522, describing compositions of RN 340008-58-4, Pyrimidine, 4-chloro-6-phenyl-2-[4-(trifluoromethyl)phenyl]-,

Art Unit: 1624

, as autoimmune inflammatory disease remedies.

Claims 1, 11, 13, 14 and 31 are rejected under 35 USC 102(e) over Nichols, et al., WO 2005020913, entitled to the date of 20030825, describing compositions of RN 160522-88-3, Pyrimidine, 2,4-bis[4-(4,5-dihydro-1H-imidazol-2-yl)phenyl]-,

RN 160522-89-4, Pyrimidine, 2,4-bis[4-(1,4,5,6-tetrahydro-2-pyrimidinyl)phenyl]-,

, for treatment of neoplasms.

Claims 1, 11, 13, 14, 31 and 33 are rejected under 35 USC 102(e) over Nunes, et al., WO 2005009443, entitled to the date of 20030624, describing compositions of RN 1058628-44-6,

, for treatment of inflammatory diseases.

### Response to 10-06-2008 Comments

Applicants submit that art disclosing compound having a -C(O)- moiety directly

attached to the central pyrimidine ring at the position corresponding to R3 of the present claims do not anticipate the present claims because such moieties are not within the scope of the R3 definition. This is correct. Rejections under 35 USC 102 over such references have been withdrawn

Applicants submit that US 5849758 and 5824624 do not anticipate the claims because they disclose herbicidal rather than pharmaceutical compositions. Rejections under 35 USC 102 over these references have been withdrawn.

Applicants submit that amendments to the present claims obviate the remaining rejections under 35 USC 102. This is incorrect. Rejections under 35 USC 102 over the following references are maintained for reasons stated above:

- Cai, et al., US 7226927, and
- Fauran, et al., US 4041030.

Additional rejections under 35 USC 102 have been entered as noted above.

### Rejections Under 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1624

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et al., Acta Polon. Pharma. (1994), 51(1), 59-62, describing antibacterial compositions of

and 4-Cl, 3-F (II), as well for their Et esters; exemplified by RN 94036-93-8, 5-Pyrimidinecarboxylic acid, 4-[(2-chlorophenyl)amino]-6-methyl-2-phenyl-, ethyl ester,

. The Cieplik compositions are structural homologs and

Art Unit: 1624

position isomers of the present compounds when R2 can be -C(O)OR6 and when the bridging amine can be alkylated.

It would have been obvious to one of ordinary skill in the art when the present invention was made to modify the Cieplik compounds to prepare structural homologs and position isomers thereof. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous and position isomeric compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous and position isomeric to prior art compounds are prima facie obvious, absent a showing of unexpected results.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.

In re Payne, 203 USPQ 245, 254 (CCPA 1979). See also In re Papesch, 137 USPQ 43 (CCPA 1963) and In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed in MPEP § 2144) for an extensive case law review pertaining to obviousness based on close structural chemical compound similarity. See also MPEP § 2144.08, ¶ II.A.4(c). Compounds that are homologs (compounds differing regularly by successive addition of the same chemical group, e.g., by CH3- groups) and position isomers (compounds differing by an adjacent or near adjacent functional group), as here, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 195 USPQ 426 (CCPA 1977).

Art Unit: 1624

Ohkubo, et al., Chem. & Pharm. Bull. (1994), 42(6), 1279-85, describing cerebral protective compositions of 5-(4-methylpiperazin-1-ylcarbonyl)-4-(4-nitrobenzoyl)-2-phenylpyrimidine

RN 116904-26-8, Piperazine, 1-methyl-4-[[6-methyl-4-[(4-nitrophenyl)thio]-2-phenyl-5-pyrimidinyl|carbonyl|-,

. Ohkubo compositions are structural homologs and

position isomers of the present compounds when R2 can be -C(O)R6. See the rejection of Cieplik, Acta Polon. Pharma. (1994) under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Machon, et al., PL 130888, published 19840929, describing pathogenic compositions of RN 94036-97-2, 5-Pyrimidinecarboxylic acid, 4-[(4-chlorophenyl)amino]-6-methyl-2-phenyl-,

Art Unit: 1624

. Machon PL 130888 compositions are structural

homologs and position isomers of claimed compounds when R2 can be –C(O)OR6 and when the bridging amine can be alkylated. See the rejection of Cieplik, Acta Polon.

Pharma. (1994) under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Machon, et al., Eur. J. Med. Chem. (1984), 19(4), 359-63, describing antibacterial compositions of

, wherein in For-

mula I, R = OEt, OH, and wherein in Formula II R = OH, NHEt, NEt2, NHC6H4OEt-4, NHC6H4Cl-4; R1 = H, 4-Cl; R2 = H, 4-OEt, 4-Cl, Cl, 3-Cl, 2-Cl, 3-CF3; see RN 94037-15-7, 5-Pyrimidinecarboxylic acid, 4-methyl-2-phenyl-6-(phenylamino)-, ethyl ester,

. Machon Eur. J. Med. Chem. (1984) compositions are structural homologs and position isomers of claimed compounds when R2 can be –C(O)R6 and when the bridging amine can be alkylated. See the rejection of Cieplik, Acta Polon.

Art Unit: 1624

Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14, 31 and 33 are rejected under 35 USC 103(a) over Kim, et al., US 3860596, issued 19750114, describing CNS depressant and anti-inflammatory compositions comprising 2-aryl-4-substituted-amino-5-pyrimidyl compounds (col. 1, lines 26-67, inter alia,) exemplified by RN 55914-58-4, 5-Pyrimidinecarboxylic acid, 4-methyl-2-phenyl-6-[[3- (trifluoromethyl)phenyl]amino]-,

. Kim compositions are structural homologs and

position isomers of claimed compounds when R2 can be -C(O)OR6 and when the bridging amine can be alkylated. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-8, 10, 11, 13, 14 and 31 are rejected under 35 USC 102(b) over Takatani, et al., JP 63107966, published 19880512, describing compositions of

for treating cerebral blood vessel diseases and disorders, in which

Ar = (nitro or habalkyl)aryl, fused benzene-heterocyclyl containing N or O; X = bond,

Art Unit: 1624

lower hydroxyalkylene, lower alkenylene, NH, S, CO; R1 = (esterified) CO2H, lower hydroxyalkyl, lower haloalkyl, (N-substituted) CONH2 or lower aminoalkyl; R2 = H, lower alkyl; optionally R1R2 completing (substituted) N-containing heterocycle; R3 = aryl; exemplified by RN 116904-26-8, Piperazine, 1-methyl-4-[[6-methyl-4-[(4-nitrophenyl)thio]-2-phenyl-5-pyrimidinyl]carbonyl]-,

. Takatani, JP 63107966 compositions are structural

homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et al., Acta Polon. Pharm. (2003), 60(6), 487-492, describing compositions of RN 164926-93-6, 4-pyrimidinamine, 5-(chloromethyl)-N-(4-chlorophenyl)-6-methyl-2-phenyl-,

, showing antibacterial and antifungal activity. Cieplik.

Acta Polon. Pharm. (2003), compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharm. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position

Art Unit: 1624

isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et al., Bollet. Chim. Farm. (2003), 142(4), 146-150, describing compositions of RN 154957-59-2, 5-Pyrimidinemethanol, 4-methyl-2-phenyl-6-(phenylamino)-,

, having antibacterial activity. Cieplik, Bollet, Chim. Farm.

(2003), compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et al., PL 194083, published 20070430, describing compositions of RN 154957-61-6, 5-Pyrimidinemethanol, 4-[(4-chlorophenyl)amino]-6-methyl-2-phenyl-,

, with immunotropic activity. Cieplik, PL 194083,

compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et

Art Unit: 1624

al., Sci. Pharm. (2002), 70(3), 245-252, describing compositions of RN 515167-37-0, 5-Pyrimidinemethanamine, 4-[(2-bromophenyl)aminol-6-methyl-2-phenyl-,

, having antibacterial properties. Cieplik, Sci. Pharm.

(2002), compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et al., Archiv der Pharm. (Weinheim, Germ.) (1997), 330(8), 237-241, describing antibacterial compositions of RN 198978-67-5, 4-Pyrimidinamine, N-(3,5-dichlorophenyl)-6-methyl-5- [(oxiranylmethoxy)methyl]-2-phenyl-,

. Cieplik, Archiv der Pharm. 1997,

compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et

Art Unit: 1624

al., Bollet. Chim. Farm. (1996), 135(8), 459-464, describing antibacterial compositions of RN 186804-30-8, 5-Pyrimidinemethanol, 4-[(4-methoxyphenyl)amino]-6-methyl-2-phenyl-,

compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Machon, et al., PL 164076, published 19940630, describing immunostimulant compositions of 2-phenyl-4-(4'-chlorophenylamino)-6-methyl-5-(hydroxymethyl)pyrimidine,

. Machon, PL 164076, compositions are

structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Cieplik, et al., Farmaco (1995), 50(2), 131-6, Describing immunomodulatory compositions of RN

Art Unit: 1624

164927-13-3, 4-Pyrimidinamine, 6-methyl-5-[(3-methylbutoxy)methyl]-N-(4-methylphenyl)-2-phenyl-,

compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Mincheva,
Doklady Bolgarskoi Akademii Nauk (1980), 33(7), 925-7, describing bactericidal
compositions of

Ph, 2-naphthyl, 4-Me2NC6H4; exemplified by RN 76851-25-7, 5-pyrimidinecarbonitrile,

, iii which it = 2-01, 0-01, 4-01, it i = 11, 0-141e, 2-0141e, it2 =

4-(4-chlorophenyl)-6-[(3-methylphenyl)amino]-2-phenyl-,

. Mincheva compositions are structural homologs

Art Unit: 1624

and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Nieland, et al., WO 2004032716, entitled to the date of 20031008, describing compositions of RN 330819-79-9, 4-Pyrimidinamine, 6-methyl-N-(4-nitrophenyl)-2-phenyl-5-(2-propen-1-yl)-,

for regulation of lipid and cholesterol uptake.

Nieland compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of the obviousness of homologs and position isomers.

Claims 1-7, 11, 13, 14 and 31 are rejected under 35 USC 103(a) over Zhu, et al., WO 2005007143, entitled to the date of 20030714, describing compositions of RN 825651-37-4, 2H-oxacyclotetradecino[4,3-d]oxazole-2,6,14(1H,7H)-trione, 8-[(2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-4-ethyldecahydro-11-methoxy-3a,7,9,11,13,15-hexamethyl-1-[[(4-methyl-2-phenyl-5-pyrimidinyl)methyl]-amino]-10-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-, (3aS,4R,7R,8S,9S,10R,11R,13R,15R,15R)-

Page 21

Application/Control Number: 10/595,734

Art Unit: 1624

treat tuberculosis. Zhu compositions are structural homologs and position isomers of claimed compounds. See the rejection of Cieplik, Acta Polon. Pharma. (1994), under 35 USC 103(a) above for the discussion of homolog and position isomer obviousness.

# Objectionable Claims

Claims 1-11, 13, 14 and 31-36 are objectionable as directed to elected and nonelected subject matter. They should be amended to recite only elected subject matter, as set forth above. Art Unit: 1624

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle

2/27/2009

/James O. Wilson/ Supervisory Patent Examiner, Art Unit 1624